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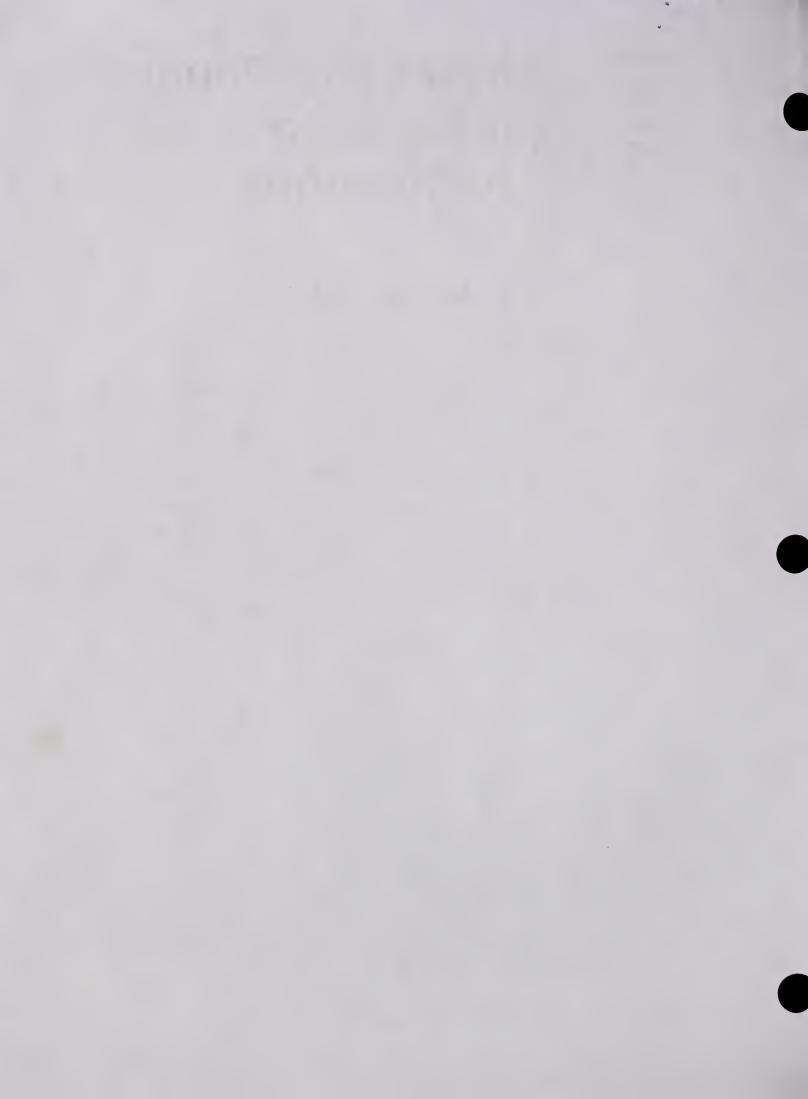
Food Safety and Inspection Service

Inspection Operations

June 19, 1996

Meat and Poultry NAT'L ACRIC LIBRARY INSPECTION Regulations

Change 96-1



UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC CHANGE TRANSMITTAL SHEET CHANGE 96-1 MEAT AND POULTRY INSPECTION REGULATIONS DIRECTIVE REVISION OTHER 6/19/96

I. PURPOSE

This document transmits changes to Parts 306, 317, 320, 327 and 381 of the MPI Regulations. These changes was published in the <u>Federal Register</u> on December 29, 1995 (60 FR 67444, Docket No. 92-012F), titled <u>Prior Labeling Approval System.</u>

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove

Pages v, vi, vii, viia, 17, 18, 84c, 84d, 84e, 85, 86, 93, 94, 154a, 193, 194, 196c and 196d

<u>Insert</u>

Pages v, vi, vii, viia, 17, 18, 84c, 8ed, 84e, 85, 86, 93, 94, 154a, 193, 194, 196c, and 196d

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Pages v, vi, 21, 22, 66a, 66b, 67, 68, 68a, 68b, 69, 70, 97, 98, 98a, 111, 112, 112c and 112d

EFFECTIVE DATE: 7/1/96

Paula M. Cohen, Director Regulations Development

Policy, Evaluation and Planning Staff

Attachment

This covers changes effective as of July 1, 1996.

DISTRIBUTION: M91, M93, M94, M95, CM3,

S03, ABB, TRA, PRD, Inspection Offices

OPI: FLD/RP

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§ 306.1 Designation of circuit supervisor and assistants.

The Administrator shall designate a circuit supervisor of the inspection in each circuit, and assign to said inspector such assistants as may be necessary.

§ 306.2 Program employees to have access to establishments.

For the purpose of any examination or inspection necessary to prevent the use in commerce of any adulterated product, Program employees shall have access at all times, by day or night, whether the establishment is operated or not, to every part of any official establishment to which they are assigned. Access to establishments is also authorized in accordance with section 202 of the Act and the regulations in Part 320 of this subchapter.

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession, and which he shall wear in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle him to admittance at a all regular entrances and to all parts of the establishment and premises to which he is assigned.

- § 306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product form official establishments.
- (a) Except as specifically authorized by the Administrator, no Program employee shall be detailed for duty at an establishment where any member of his family is employed by the operator of the establishment, or any tenant or subsidiary of such operator nor shall any circuit supervisor or other employee acting in a supervisory capacity be continued on duty at a circuit where any member of his family is so employed at any establishment under his jurisdiction. Program employees are forbidden to solicit, for any person, employment at any official establishment, or by any officer, manager, or employee thereof.
- (b) Program employees shall not procure product from any official establishment or any other establishment if its operations or products are inspected or regulated under the Poultry Products Inspection Act or the Agricultural Marketing Act of 1946, as amended, or any other law administered by the Department unless the store or outlet from which the purchase is made is open to the general public and the price paid by such employee is the same as the price paid by the general public. Program employees must pay, and obtain receipts for money paid to such establishments for all such product and keep such receipts subject to inspection by supervisory employees or other authorized Department employees.

§ 306.5 Appeals.

Any appeal from a decision of any Program employee shall be made to his/her immediate supervisor having jurisdiction aver the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

PART 307-FACILITIES FOR INSPECTION

AUTHORITY: 7 U.S.C. 394; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 307.1 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the circuit supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such clothes changing facilities are deemed necessary by the circuit supervisor. At the discretion of the Administrator, small plants requiring the services of less than one full time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

§ 307.2 Other facilities and conditions to be provided by establishment.

When required by the circuit supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions, shall be provided by each official establishment:

- (a) Satisfactory pens, equipment, and assistants for conducting antemortem inspection and for separating, marking and holding apart from passed livestock those marked "U.S. suspect" and those marked "U.S. condemned" (pens, alleys, and runways shall be paved, drained, and supplied with adequate hose ,connections for cleanup purposes);
 - (b) Sufficient light to be adequate for proper conduct of inspection;
- (c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, and viscera, and all parts and blood to be used in the preparation of meat food products or medical products, until after the post-mortem examination is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor; and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;
- (d) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;
- (e) Watertight metal trucks or receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned; such

- (3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.
- (4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge mark such brand or other marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015.)

* § 317.4 Labeling approval.

- (a) No labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 317.5(b). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. Such records shall be made available to any duly authorized representative of the Secretary upon request.
- (b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 317.4(d), for all products, except as provided in § 317.5(b)(2)-(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.
- (c) All labeling required to be submitted for approval as set forth in § 317.4(a) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate form) for a product produced in other establishments that are owned by the corporation.
- (d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in § 317.2. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

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- (e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 317.5(b)(7).
- (f) (1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food * * Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

(q) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and

316 of this subchapter.

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§ 317.5 Generically approved labeling.

- (a) (1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to *
- the Food Safety and Inspection Service in Washington or the field, provided

the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in § 317.2, and is not otherwise *

false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 of this subchapter, as required in § 317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 335.12.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in part 319 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient * content claims, health claims, negative claims, geographical origin claims, or quarantees, or which is not a domestic product labeled in a foreign language;

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- (2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;
- (3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;
- (4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 316.13;
- (5) Labeling for products not intended for human food, provided they comply with part 325 of this subchapter;
- (6) Meat inspection legends, which comply with parts 312 and 316 of this subchapter;
- (7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;
 - (8) Labeling for consumer test products not intended for sale; and
- (9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:
- (i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;
- (ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";
- (iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);
- (iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);
- (v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;
- (vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;
- (vii) Any change in the name or address of the packer, manufacturer ordistributor that appears in the signature line;



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(viii) Any change in the net weight, provided the size of the net weight
  statement complies with § 317.2;
     (ix) The addition, deletion, or amendment of recipe suggestions for the
  product;
     (x) Any change in punctuation;
     (xi) Newly assigned or revised establishment numbers for a particular
*
  establishment for which use of the labeling has been approved by the Food
  Labeling Division, Regulatory Programs;
     (xii) The addition or deletion of open dating information;
     (xiii) A change in the type of packaging material on which the label is
  printed;
     (xiv) Brand name changes, provided that there are no design changes, the
  brand name does not use a term that connotes quality or other product
  characteristics, the brand name has no geographic significance, and the
  brand name does not affect the name of the product;
          The deletion of the word "new" on new product labeling;
     (xvi) The addition, deletion, or amendment of special handling
  statements, provided that the change is consistent with § 317.2(k);
     (xvii) The addition of safe handling instructions as required by
  § 317.2(1);
     (xviii) Changes reflecting a change in the quantity of an ingredient
  shown in the formula without a change in the order of predominance shown on
  the label, provided that the change in quantity of ingredients complies with *
  any minimum or maximum limits for the use of such ingredients prescribed in
  parts 318 and 319 of this subchapter;
     (xix) Changes in the color of the labeling, provided that sufficient
  contrast and legibility remain;
     (xx) A change in the product vignette, provided that the change does not
  affect mandatory labeling information or misrepresent the content of the
  package;
     (xxi) A change in the establishment number by a corporation or parent
  company for an establishment under its ownership;
     (xxii) Changes in nutrition labeling that only involve quantitative
  adjustments to the nutrition labeling information, except for serving
  sizes, provided the nutrition labeling information maintains its accuracy
  and consistency;
     (xxiii) Deletion of any claim, and the deletion of non-mandatory features *
  or non-mandatory information; and
     (xxiv) The addition or deletion of a direct translation of the English
  language into a foreign language for products marked "for export only."
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§ 317.6 Approved labels to be used only on products to which they are applicable.

Labels shall be used only on products for which they are approved, and only if they have been approved for such products in accordance with § 317.3: Provided, That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of the operator

of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and Part 319 of this subchapter. The Administrator may upon the show of good cause grant individual extension of time as he deems necessary.

§ 317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.

Labels to be affixed to packages of products for foreign commerce may be printed in a foreign language and may show the statement of the quantity of contents in accordance with the usage of the country to which exported and other deviations from the form of labeling required under this part may be approved for such product by the Administrator in specific cases: Provided,

(a) That the proposed labeling accords to the specifications of the

foreign purchaser,

(b) That it is not in conflict with the laws of the country to which

the product is intended for export, and

- (c) That the outside container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of this subchapter apply. The inspection legend and the establishment number shall in all cases appear in English but in addition, may appear literally translated in a foreign language.
- § 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.
- (a) No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading.

(b) The labels and containers of product shall comply with the following

provisions, as applicable:

§ 317.13 Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter.

- * § 317.14 [Reserved]
 - § 317.15 [Reserved]
 - § 317.16 Labeling and containers of custom prepared products.

Products that are custom prepared under § 303.1(a)(2) of this subchapter must be packaged immediately after preparation and must be labeled (in lieu of information otherwise required by this Part 317) with the words "Not for Sale" in lettering not less than three-eighth inch in height. Such exempted custom prepared products or their containers may bear additional labeling provided such labeling is not false or misleading.

- § 317.17 Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.
- (a) With respect to sections 1(n), (7), (9), and (12) of the Act and § 317.2, any substance mixed with another substance to cure a product must be identified in the ingredients statement on the label of such product. For example, curing mixtures composed of such ingredients as water, salt, sugar, sodium phosphate, sodium nitrate, and sodium nitrite or other permitted substances which are added to any product, must be identified on the label of the product by listing each such ingredient in accordance with the provisions of § 317.2.
- (b) Any product, such as bacon or pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c) (1) of this Part and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term "Uncured" as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

- (c) (l) Products described in paragraph (b) of this section or § 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement "No Nitrate or Nitrite Added." This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.
- (2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement "Not Preserved-Keep Refrigerated Below 40° F. At All Times" unless they have been thermally processed to F_o 3 or more; they have been fermented or pickled to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.
- (3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

§ 317.18 Quantity of contents labeling.

Sections 317.18 through 317.22 of this Part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with section 317.2(h) of this Part.

- § 317.19 Definitions and procedures for determining net weight compliance.
- (a) For the purpose of §§ 317.18 through 317.22 of this Part, the reasonable variations allowed, definitions, and procedures to be used in determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, "Checking the Contents of Packaged Goods," Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1, 3, and 4 requirements listed in paragraphs (b) and (c) of this section. Those provisions incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the Federal Register. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. It is also available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, D.C. 20408.

(§ 320.1(b) continued)

- (6) Records of canning as required by Subpart G of this Subchapter A, 9 CFR Chapter III.
- (7) Sample results and calculation results as required by processing procedures to destroy trichinae in § 318.10(c)(3)(iv) (Methods 5 and 6).
- (8) Records of nutrition labeling as required by Subpart B, Part 317, of this subchapter.

(9) Records as required in § 318.23(b) and (c).

- (10) Records of calcium content in meat derived from advanced meat/bone separation machinery and meat recovery systems as required by § 318.24 of this subchapter.
- * (11) Records of all labeling, along with the product formulation and * processing procedures, as prescribed in § 317.4 and § 317.5.

(Approved by the Office of Management and Budget under OMB #0583-0015)

§ 320.2 Place of maintenance of records.

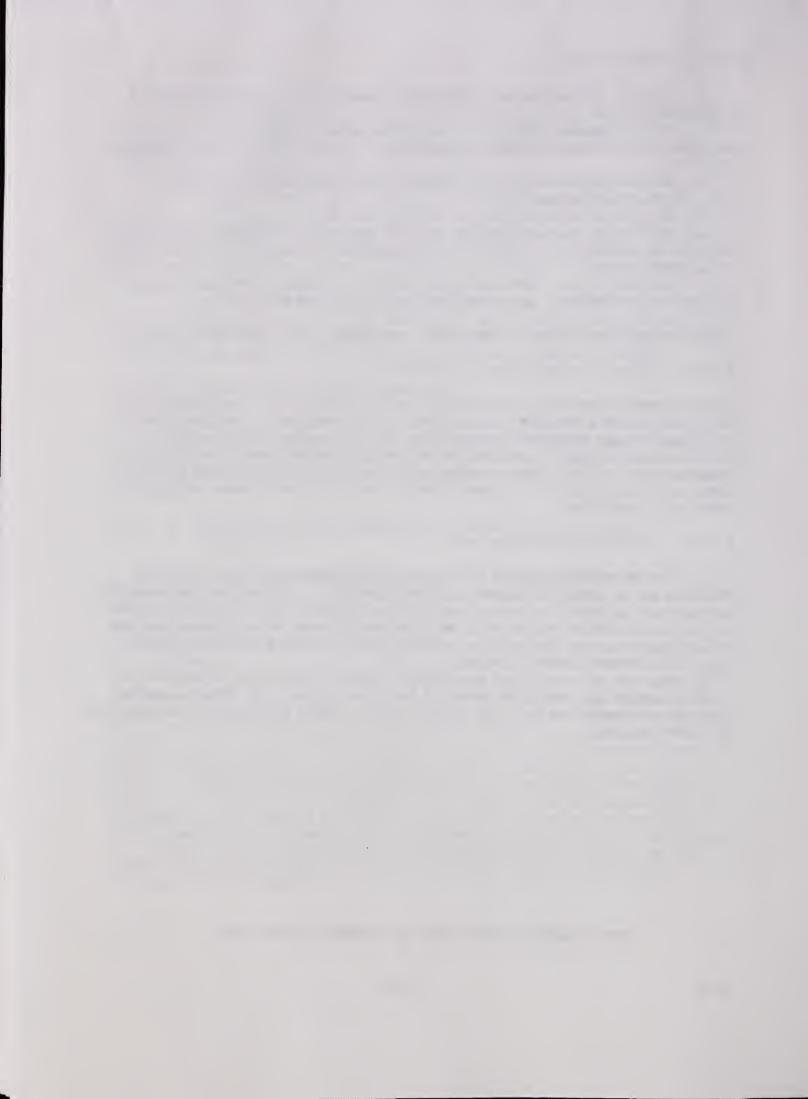
Every person engaged in any business described in § 320.1 and required by this part to keep records shall maintain such records at the place where such business is conducted except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 320.3 Record retention period.

- (a) Every record required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.
- (b) Records of canning as required in Subpart G of this Subchapter A, 9 CFR Chapter III, shall be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) shall be retained as required by those sections.

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- § 327.14 Marking of products and labeling of immediate containers thereof for importation.
- (a) Product which is offered for importation, and which is susceptible of marking, shall, whether or not enclosed in an immediate container, bear the name of the country of origin, preceded by the words "product of"; the establishment number assigned by the foreign meat inspection system and certified to the Program; and such other markings as are necessary for compliance with Part 316 of this subchapter. When such markings are imprints of stamps or brands made with branding ink, such ink shall be harmless and shall create permanent imprints. In case the name of the country of origin appears as part of an official mark of the national foreign government and such name is prominently and legibly displayed, the words "product of" may be omitted.

(b) In addition to the marking of products required under paragraph (a) of this section, the immediate container of any product offered for

importation:

- (1) Shall bear a label showing in accordance with § 317.2 of this subchapter all information required by that section (except that the establishment number assigned by the foreign meat inspection system and certified to the Program and the official inspection mark of the foreign meat inspection system shall be shown instead of the official inspection legend of the United States) and in addition the name of the country of origin preceded by the words "product of," immediately under the name or descriptive designation of the product as required by § 317.2: Provided, That such establishment number may be omitted from a label lithographed directly on a can if said number is lithographed or embossed elsewhere on the can; and
- (2) Shall, if such immediate container is a sealed metal container, have the establishment number assigned by the foreign meat inspection authority and certified by the Program embossed or lithographed on the sealed metal container, and such establishment number shall not be covered or obscured by any label or other means.
 - (c) All marks and other labeling for use on or with immediate containers,
- as well as private brands on carcasses or parts of carcasses, shall be
 approved by the Food Safety and Inspection Service in accordance with part 317 of this subchapter before products bearing such marks, labeling,
- or brands will be entered into the United States. The marks of inspection of foreign systems embossed on metal containers or branded on carcasses or

parts thereof need not be submitted to the Food Safety and Inspection

* Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard

* containers of foreign products without such marks of inspection being

- * submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.
 - § 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.
 - (a) The outside container in which any immediate container of foreign product is shipped to the United States shall bear, in English, in a prominent and legible manner:

(§ 327.15(a) continued)

- (1) The name or descriptive designation of the product in accordance with § 317.2 of this subchapter;
 - (2) The name of the country of origin; and
- (3) The establishment number assigned by the foreign meat inspection system and certified to the Program.
- (b) All labeling used with an outside container of foreign product must be approved in accordance with Part 317 of this subchapter.
- (c) Except for product offered for entry from Canada, all outside containers of products which have been inspected and passed in accordance with this part shall be marked by a Program import inspector or under a Program import inspector's supervision with the official import meat inspection mark prescribed in § 327.26.
- § 327.16 Small importations for importer's own consumption; requirements.

Any product in a quantity of 50 pounds or less which was purchased by the importer outside the United States for his/her own consumption, is eligible to be imported into the United States from any country without compliance with the provisions in other sections of this part but subject to applicable requirements under other laws, including the regulations in Part 94 of this title. However, Program employees may inspect any product imported under this section to determine whether it is within the class eligible to be imported under this paragraph.

- § 327.17 Returned U.S. inspected and marked products.
- U.S. inspected and passed and so marked products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification to and approval of the Deputy Administrator, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, in specific cases.
 - § 327.18 Products offered for entry and entered to be handled and transported as domestic; exception.
- (a) All products, after entry into the United States, shall be deemed and treated as domestic products and shall be subject to the applicable provisions of the Act and the regulations in this subchapter and the applicable requirements under the Federal Food, Drug and Cosmetic Act, except that products imported under § 327.16 are required to comply only with the requirements of that Act and § 327.16 of this subchapter.
- (b) Products entered in accordance with this part may, subject to the provisions of Part 318 of this subchapter, be taken into official establishments and be mixed with or added to any product in such establishments which has been inspected and passed therein.
- (c) Imported product which has been inspected, passed, and marked under this part may be transported in the course of importation or subsequently in commerce only upon compliance with Part 325 of this subchapter.

(i) The average PFF percentage of the five randomly selected sample units is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105 of this subchapter, or

(ii) The product is relabeled under the supervision of a program employee so that it conforms to the provisions of § 319.104 or § 319.105 of

this subchapter.

(2) If product from a foreign establishment is subject to retention procedures under this section, the foreign establishment may be returned to

normal monitoring procedures when:

(i) Ten consecutively presented lots of that cured pork product from that establishment have been sampled as provided in paragraph (c) (1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (50 in all) is above the

Absolute Minimum PFF Percentage.

- (3) If a country is subject to retention procedures under this section, the country shall be returned to normal monitoring procedures when:
- (i) Twenty-five consecutively presented lots of cured pork product have been sampled as required in paragraph (c) (1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and
- (ii) The PFF percentage of each sample unit (125 in all) is above the Absolute Minimum PFF Percentage; and
- (iii) Both of the PFF Standardized Averages for 36 consecutive lots are in the required percentage of the Normal distribution; and
- (iv) Both of the PFF Standardized Averages for 100 consecutive lots are zero or higher.
- (4) The sample units collected under retention procedures as provided in paragraph (c)(2) of this section will not be included in the PFF standardized averages for 36 and 100 consecutive lots.
- (d) <u>Adulterated and Misbranded Products</u>. Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).
- (e) Activities requiring additional inspectional supervision, such as relabeling, shall be at the importer's expense. In addition, if the importer wishes, he or she may have samples analyzed at an accredited laboratory.

§327.24 Appeals; how made.

Any appeal from a decision of any program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice. * * *

- § 327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.
- (a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this section shall be considered denatured for the purposes

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of the regulations in this part, except as otherwise provided in Part 314 of this subchapter for articles condemned at official establishments or at official import inspection establishments.

- (1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under Part 314 of this subchapter if they were at an official establishment or at an official import inspection establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases. 1
- (2) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and except as provided in paragraph (3) and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases. Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91). 2
- (3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring.
- (4) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product, may be used in lieu of the agents prescribed in paragraph (a) (2) of this section.

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^{1/} Information as to approval of any proprietary denaturing substance may be obtained from the Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

^{2/} Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register Library.

| * | 381.132 | Labeling approval. * |
|---|---------|--|
| * | 381.133 | Generically approved labels. * |
| * | 381.134 | Requirement of formulas and analyses. * |
| | 381.135 | Irradiated poultry product. |
| | 381.136 | Affixing of official identification. |
| | | |
| | 381.137 | Evidence of labeling and devices approval. |
| | 381.138 | Unauthorized use or disposition of approved labeling or devices. |
| | 381.139 | Removal of official identifications. |
| | 381.140 | Relabeling poultry products. |
| * | 381.141 | [Reserved] * |
| | 381.143 | [Reserved] |
| | 381.144 | Packaging materials. |
| | Subpart | : O-Entry of Articles Into Official Establishments; Processing |
| | | Inspection and Other Reinspections; Processing |
| | | Requirements |
| | | Requirements |
| | 381.145 | Poultry products and other articles entering or at official |
| | 3011113 | establishments; examination and other requirements. |
| | 381.146 | Sampling at official establishments. |
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| | 381.147 | Restrictions on the use of substances in poultry products. |
| | 381.148 | Processing and handling requirements for frozen poultry products. |
| | 381.149 | Irradiation of poultry product to control foodborne pathogens. |
| | 381.150 | Requirements for the production of poultry breakfast strips; |
| | | poultry rolls, and certain other poultry products. |
| | 381.151 | Adulteration of product by polluted water; procedure for handling. |
| | 381.152 | Preparation in an official establishment of articles not for human food. |
| | 381.153 | Accreditation of chemistry laboratories. |
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| | | Subpart P-Definitions and Standards of Identity |
| | | or Composition |
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| | | Poultry meat content standards for certain poultry products. |
| | 381.156 | |
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| | 381.158 | Poultry dinners (frozen) and pies. |
| | 381.159 | Poultry rolls. |
| | 381.160 | (Kind) burgers; (Kind) patties. |
| | 381.161 | (Kind) A La Kiev. |
| | 381.162 | "(Kind) steak or fillet." |
| | 381.163 | "(Kind) baked" or "(Kind) roasted." |
| | 381.164 | "(Kind) barbequed." |
| | 381.165 | "(Kind) barbequed prepared with moist heat." |
| | 381.166 | Breaded products. |
| | | _ |
| | 381.167 | Other poultry dishes and specialty items. |
| | 381.168 | Maximum percent of skin in certain poultry products. |
| | 381.169 | Ready-to-cook poultry products to which solutions are added. |
| | 381.170 | Standards for kinds and classes, and for cuts of raw poultry. |
| | 381.171 | Definition and standards for "Turkey Ham." |
| | 381.173 | Mechanically Separated (Kind of Poultry). |
| | 381.174 | Limitations with respect to use of Mechanically Separated |
| | 302.27 | (Kind of Poultry) |
| | | (ILIIA OF FOATOFY) |
| | | Subpart Q-Records, Registration, and Reports |
| | 201 175 | Records required to be kept. |
| | 381.175 | records required to be rept. |

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| 381.176 381.177 | Place of maintenance of records. Record retention period. |
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| 381.178 | Access to and inspection of records, facilities and inventory; copying and sampling. |
| 381.179 381.180 | Registration. Information and reports required from official establishment |
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| 381.187 | [Reserved] |
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| 381.190 | Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements. |
| 381.191 | Distribution of Inspected products to small lot buyers. |
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| 381.194 | Transportation and other transactions concerning dead, dying, |
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| | Subpart T-Imported Poultry Products |
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| 381.199 | Inspection of imported poultry products. |
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| 381.201 | Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition. |
| 381.202 | Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made: denaturing procedures. |
| | made: delatificid procedifes |

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§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to

political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: Provided, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when required, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of \$9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection. * * *

Subpart G-Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) Inspector's Office. Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this

section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) Facilities for ante-mortem inspection. Batteries, coops, or other facilities in which live poultry is presented for ante-mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out an adequate inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for

SIS in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c) (1) (iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station

and 16 feet for two-inspection stations.

- (iii) Selectors or "kickouts" shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspector. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.
- (iv) Each inspector's station shall meet the requirements specified in § 381.53. The station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with 1/2-inch foot bumpers and both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities complying with section 381.53(g)(4) of this Part shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(c) A calendar date may be shown on labeling when declared in accordance

with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date in terms of "packing" date, "sell by" date, or "use before" date, with or without a further qualifying phrase, e.g., "For Maximum Freshness" or "For Best Quality", and such phrases shall

be approved by the Administrator as prescribed in § 381.132.

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground and formed poultry products, as permitted in § 381.147 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

§ 381.130 False or misleading labeling or containers; orders to withhold from use.

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the Circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

- § 381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.
- (a) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However,

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- (1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the devices of the type and quantity listed on the certificate.
- (2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the marking device manufacturer.
- (3) The manufacturer of the marking devices shall engrave or otherwise mark each marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the marking devices to the Program employee whose name and address are given on the certificate as the recipient.
- (4) In order that all such marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such marking device that does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such marking device with a permanent identifying number.

(The recordkeeping requirements under this section have been approved by the Office of Management and Budget under OMB # 0583-0015.)

§ 381.132 Labeling approval.

- (a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 381.133(b)(2)-(9). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.
- (b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 381.132(d), for all products, except as provided in § 381.133(b)(2)-(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.
- (c) All labeling required to be submitted for approval as set forth in § 381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

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(d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are hand drawn, computer generated or other reasonable

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facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

- (e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(9).
- (f) (1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:
 - (i) The proposed labeling would not misrepresent the product;
- (ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
- (iii) Denial of the request would create undue economic hardship;
- (iv) An unfair competitive advantage would not result from the granting of the temporary approval.
- (2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

§ 381.133 Generically approved labeling.

- (a) (1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.
- (2) The Food Safety and Inspection Service shall select samples of * generically approved labeling from the records maintained by official * establishments and establishments certified under foreign inspection * systems, in accordance with subpart T of this part, as required in * \$ 381.132, to determine compliance with labeling requirements. Any finding * of false or misleading labeling shall institute the proceedings prescribed * in § 381.233.
- (b) Generically approved labeling is labeling which complies with the following:
- (1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

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- (2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;
- (3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;
- (4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;
- (5) Labeling for products not intended for human food, provided they comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);
- (6) Poultry inspection legends, which comply with subpart M of this part;
- (7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;
 - (8) Labeling for consumer test products not intended for sale; and
- (9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:
- (i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;
- (ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";
- (iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);
- (iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

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- (v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;
- (vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;
- (vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;
- (viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

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(ix) The addition, deletion, or amendment of recipe suggestions for
    the product;
         (x) Any change in punctuation;
         (xi) Newly assigned or revised establishment numbers for a particular *
   establishment for which use of the labeling has been approved by the Food
   Labeling Division, Regulatory Programs;
         (xii) The addition or deletion of open dating information;
         (xiii) A change in the type of packaging material on which the label
   is printed;
         (xiv) Brand name changes, provided that there are no design changes,
   the brand name does not use a term that connotes quality or other product
   characteristics, the brand name has no geographic significance, and the
   brand name does not affect the name of the product;
         (xv) The deletion of the word "new" on new product labeling;
         (xvi) The addition, deletion, or amendment of special handling
   statements, provided that the change is consistent with § 381.125(a);
         (xvii) The addition of safe handling instructions as required by
   § 381.125(b);
         (xviii) Changes reflecting a change in the quantity of an ingredient
   shown in the formula without a change in the order of predominance shown
   on the label, provided that the change in quantity of ingredients complies
   with any minimum or maximum limits for the use of such ingredients
   prescribed in § 381.147 and subpart P of this part;
         (xix) Changes in the color of the labeling, provided that sufficient
   contrast and legibility remain;
         (xx) A change in the product vignette, provided that the change does
   not affect mandatory labeling information or misrepresent the content of
   the package;
         (xxi) The addition, deletion, or substitution of the official USDA
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   poultry grade shield;
         (xxii) A change in the establishment number by a corporation or
   parent company for an establishment under its ownership;
         (xxiii) Changes in nutrition labeling that only involve quantitative
   adjustments to the nutrition labeling information, except for serving
   sizes, provided the nutrition labeling information maintains its accuracy
   and consistency;
         (xxiv) Deletion of any claim, and the deletion of non-mandatory
   features or non-mandatory information;
         (xxv) The addition or deletion of a direct translation of the English *
   language into a foreign language for products marked "for export only"; and *
         (xxvi) The addition of a descriptive term as required by
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§ 381.134 Requirement of formulas.

§ 381.129(b)(6).

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

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§ 381.135 Irradiated poultry product.

(a) The labeling of packages of poultry product irradiated in conformance with § 381.147(f)(4) of this part must bear the following logo along with a statement such as, "Treated with radiation" or "Treated by irradiation," in addition to all other labeling requirements of this subpart. The logo must be placed prominently and conspicuously in conjunction with the required statement and be colored green. The statement must appear as a qualifier contiguous to the product name and in letters of the same style, color, and type as the product name. Letters used for the qualifying statement shall be no less than one-third the size of the largest letter in the product name. Any labeling bearing the logo and any wording of explanation with respect to this logo must be proved as required by subparts M and N of this part.

(b) The product label must bear the handling statement "Keep Refrigerated" or "Keep Frozen," as appropriate, in conformance with § 381.125 of this Subpart.

(c) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the above stated requirements. Such statements must not be false or misleading.

§ 381.136 Affixing of official identification.

- (a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.
- (b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labeling or devices bearing official inspection marks is prohibited and may result in cancellation of the approval.

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(§ 381.138 continued)

(b) Labeling and containers bearing any official inspection marks, with or without the official establishment number, may be transported from one official establishment to any other official establishment, only if such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. Approved labeling and containers may be moved without restriction under this part between official establishments operated by the same person if such labeling and containers are approved for use at all such establishments. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subpart.

§ 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend shall remove or deface such legend or destroy the containers upon removal of such articles from the containers.

(b) No person shall alter, detach, deface, or destroy any official identifications prescribed in Subpart M that were applied pursuant to the regulations, unless he is authorized to do so by an inspector or this section; and no person shall fail to use any such official identification when required by this part.

§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with official labels shall be done under the supervision of an inspector pursuant to the regulations in Part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

§ 381.141 [Reserved]

§ 381.143 [Reserved]

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- (a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).
- (b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such quaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA

and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any quaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written quaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such quaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request -- a minimum of 30 days -- any applicable quaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(12) "Quarters" consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) "Breast quarter" consists of half a breast with the wing and a

portion of the back attached.

(14) "Breast quarter without wing" consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) "Leg quarter" consists of a poultry thigh and drumstick, with a

portion of the back attached.

- (16) "Thigh with back portion" consists of a poultry thigh with back portion attached.
- (17) "Legs with pelvic bone" consists of a poultry leg with adhering meat and skin and pelvic bone.
- (18) "Wing drummette" consists of the humerus of a poultry wing with adhering skin and meat attached.
- (19) "Wing portion" consists of a poultry wing except that the drummette has been removed.
- (20) "Cutup Poultry" is any cutup or disjointed portion of poultry or any edible part thereof, as described in this section.
- (21) "Giblets" consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

§ 381.171 Definition and standard for "Turkey Ham."

- (a) "Turkey Ham" shall be fabricated from boneless, turkey thigh meat with skin and the surface fat attached to the skin removed. The thighs shall be that cut of poultry described in § 381.170(b)(5) of this Part.
- (b) The product may or may not be smoked, and shall be cured using one or more of the approved curing agents as provided in § 381.147(f) of this Part. The product may also contain cure accelerators, phosphates, and flavoring agents as provided in § 381.147(f) of this Part; common salt, sugars, spices, spice extractives, dehydrated garlic, and dehydrated onions; and water for purpose of dissolving and dispersing the substances specified above.

(c) The cooked finished product weight shall be no more than the original

weight of the turkey thigh meat used prior to curing.

- (d) The product name on the label shall show the word "Turkey" in the same size, style, color, and with the same background as the word "Ham" and shall precede and be adjacent to it.
- (e) The product name shall be qualified with the statement "Cured Turkey Thigh Meat." The qualifying statement shall be contiguous to the product name, without intervening type or designs, shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.
- (f) If the product is fabricated from pieces of turkey thigh meat that result from the cutting through the muscle (as opposed the whole thighs intact or whole thighs with some incidental separation of muscle tissue during removal of the bone), the product name shall be further qualified by a descriptive statement. The product name of product fabricated from such pieces of turkey thigh meat equivalent in size to a one-half inch cube or greater shall be further qualified to specify that the product is "Chunked and Formed." The product name of product fabricated from such pieces of turkey thigh meat smaller than the equivalent of a one-half inch cube shall

be further qualified to specify that the product is "Ground and Formed" or "Chopped and Formed" as appropriate. The qualifying statement shall immediately follow and be contiguous to the statement required in paragraph (e) of this section, and shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

Subpart Q-Records, Registration, and Reports

§ 381.175 Records required to be kept.

(a) Every person within any of the classes specified in subparagraph (1), (2), or (3) of this paragraph is required by the Act to keep such records as are properly necessary for the effective enforcement of the Act:

(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a poultry products broker, wholesaler, or otherwise) or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(b) The required records are:

- (1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any poultry or poultry carcass, or part or product of a poultry carcass, is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act.
 - (i) The name or description of the poultry or other articles;
 - (ii) The net weight of the poultry or other articles;

(iii) The number of outside containers;

- (iv) The name and address of the buyer of the poultry or other articles sold by such person, and the name and address of the seller of the poultry or other articles purchased by such person;
- (v) The name and address of the consignee or receiver (if other than the buyer);
 - (vi) The method of shipment;
 - (vii) The date of shipment; and
 - (viii) The name and address of the carrier.
- (2) Guaranties provided by suppliers of packaging materials under § 381.144.
- (3) Records of canning as required by Subpart X of this Part 381, of Subchapter C, 9 CFR, Chapter III.
 - (4) Records of irradiation as required by section 381.149 of this Part.
 - (5) Records of nutrition labeling as required by Subpart Y of this Part.
- (6) Records of all labeling, along with the product formulation and * processing procedures, as prescribed in §§ 381.132 and 381.133.

(Approved by the Office of Management and Budget under OMB #0583-0015)

§ 381.176 Place of maintenance of records.

Every person engaged in any business described in § 381.175(a) shall maintain the records required by § 381.175 at the place of business where such business is conducted, except that, if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 381.177 Record retention period.

(a) Every record required to be maintained under this subpart shall be retained for a period not to exceed 2 years after December 31 of the year in which the transaction to which the record relates has occurred, and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such record under this subpart.

(b) Records of canning as required by Subpart X of this Part 381, Subchapter C, 9 CFR Chapter III, shall be retained as required in § 381.307; except that records required by § 381.302(b) and (c) shall be

retained as required by those sections.

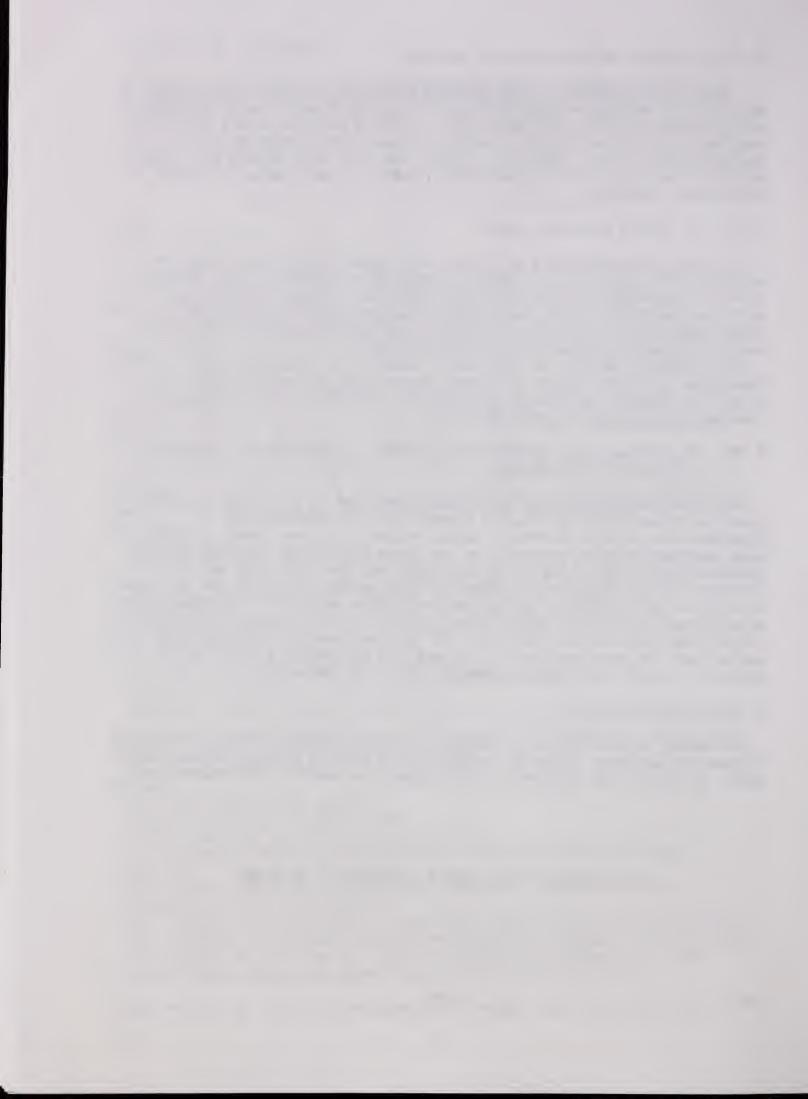
§ 381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

Every person within any of the classes specified in § 381.175(a) shall, upon the presentation of official credentials by any authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by § 381.175(b) and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records, and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

§ 381.179 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engages in business in commerce as a

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(h) The official mark for use in sealing means of conveyance used in transporting poultry products under any requirement in this part shall be the inscription and a serial number as shown below, and any seals approved by the Administrator for applying such mark shall be an official device.

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§381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.

Compartments of steamships, railroad cars, and other means of conveyance transporting any poultry product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any poultry product offered for entry into the United States, shall be maintained in a sanitary condition.

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a) (1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this Part, to the Director of

Customs at the original port of entry.

(2) When product has been identified as "U.S. refused entry," the inspector shall request the Director of Customs to refuse admission to such within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to pet food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation or to an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food Purposes. "Refused entry" product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a) (4) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to subparagraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States without the expressed consent of the Administrator, based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term "lot" shall refer to that product

^{1/} The term "F-351587" is given as an example only. The serial number of the specific seal will be shown in lieu thereof.

identified on MP Form 410 in the original request for inspection for

importation pursuant to § 381.198.

(4) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in subparagraph (2) of this paragraph for refused entry product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

- (5) If the owner or consignee fails to take the required action within the time specified under subparagraph (4) of this paragraph, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate
- (6) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative, detention in accordance with section 19 of the Act, and seizure and condemnation in accordance with section 20 of the Act.
- (b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under this subpart and subsequently designated "U.S. Refused Entry" or found in any respect not to comply with the requirements in this subpart.

(c) Except as provided in § 381.200 (a) or (b), no person shall remove or cause to be removed from any place designated as the place of inspection, any poultry product which the regulations in this subpart require to be marked in any way, unless the same has been clearly and legibly marked

in compliance with this subpart.

- (d) Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: Provided, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate supervisor of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of \$9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection. * * *
- (e) All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishments.)
- (1) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, a sufficient time to effectively destroy the product for human food food purposes and preclude

- (d) The import warning notice prescribed in §381.200(c) is an official mark.
- (e) The ordering and manufacture of brands shall be in accordance with the provisions contained in §317.3(c) of the Federal meat inspection regulations.
- (f) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports directly to an Import Field Office Supervisor; the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.
- (1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following: (i) that stamping under this part will be limited to those lots of product which can be inspected on the day that certificates for the product are examined; (ii) that all product which has been pre-stamp will be stored in the facility where the import inspection will occur; (iii) that inspection marks applied under this part will be removed fram any lot of product subsequently refused entry on the day the product is rejected; and (iv) that the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP-410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of §381.177.
- (2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this part or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writining, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping privilege was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adapted by the Administrator. The cancellation of the controlled pre-stamping, privilege will be in effect until there is a final determination of the proceeding.

(Approved by the Office of Management and Budget under control number 0583-0015)

- § 381.205 Labeling of immddiate containers of poultry products offered for entry.
- (a) Immediate containers of poultry products imported into the United States shall bear a label printed in English showing in accordance with Subpart N of this part all information required by that section (except that the inspection mark and establishment number assigned by the foreign poultry inspection system and certified to the Inspection Service shall be shown instead of the official dressed poultry identification mark or other official inspection legend, and official establishment number); and in addition the label shall show the name of the country of origin preceded by the words "Product of," which statement shall appear immediately under the name of the product.

(b) The labels shall not be false or misleading in any respect.

(c) All marks and other labeling for use on or with immediate containers
* shall be approved for use by the Food Safety and Inspection Service in
* accordance with §§ 381.132 and 381.133 before products bearing such marks
* and other labeling will be permitted for entry into the United States.

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

Shipping containers of imported poultry products are required to bear in a prominent and legible manner the name of the product, the name of the country of origin, the foreign inspection system establishment number of the establishment in which the product was processed, and the inspection mark of the courtry of origin. Labeling on shipping containers shall be examined at the time of inspection in the United States and if found to be followed as a mighanding the product shall be refused entry.

- * false or misleading, the product shall be refused entry. All labeling used
- * with a shipping container of imported poultry products must be approved in

* accordance with subpart N of this part.

§ 381.207 Small importations for consignee's personal use, display, or laboratory analysis.

Any poultry product (other than one which is forbidden entry by other Federal law or regulation) from any country in quantities of less than 50 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesame, and fit for human food, and which is not adulterated and contains no substance not permitted by the Act or regulations, may be imported into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part, except as provided in § 381.199(c):